

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Muimo et al. )  
)  
Serial No.: To be assigned )  
(Continuation of )  
PCT/GB00/00736 )  
)  
Filed: Herewith )  
)  
For: METHODS OF DETERMINING )  
ALTERED NDPK FUNCTIONS )  
AND THE DIAGNOSIS OF )  
CYSTIC FIBROSIS )  
\_\_\_\_\_ )

**PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231  
Box: Patent Application

Sir:

Please amend the above-identified patent application  
as follows:

In the Specification:

Please insert the following new paragraph on page 1,  
line 2 prior to the first paragraph:

"This application is a continuation of PCT/GB00/00736,  
filed March 2, 2000, which claims priority to U.S. Provisional  
Patent Application Serial No. 60/122,426, filed March 2, 1999,  
which are hereby incorporated by reference."

In the Claims:

Please amend claims 6, 12, 13, 20, 23, 32, 33, 36,  
39, 40, 45 and 48, cancel claims 24, 27, 38 and 42 and insert  
new claims 51-57 as follows:

6. (Amended) A method according to claim 1 wherein the epithelial cell sample from the patient is a lung cell sample or a nasal cell sample.

12. (Amended) A method according to claim 7 wherein the epithelial cell sample from the patient is a lung cell sample or a nasal cell sample.

13. (Amended) A method according to claim 7 wherein the effectiveness of a treatment for cystic fibrosis is being tested on the patient.

20. (Amended) A method according to claim 14 wherein the method is carried out *in vivo*.

23. (Amended) A compound identified by the method of claim 14.

32. (Amended) A peptide according to claim 31 which comprises SEQ. ID. NO. 1.

33. (Amended) A peptide according to claim 28 further comprising a lipid-solubilising moiety.

36. (Amended) A peptide according to claim 33 wherein the lipid-solubilising moiety is a fatty acid.

39. (Amended) A pharmaceutical formulation comprising a peptide according to claim 28 and a pharmaceutically acceptable carrier.

40. (Amended) A method of treating cystic fibrosis or a chronic sputum producing disorder, the method comprising administering to a patient an effective amount of a peptide according to claim 28.

45. (Amended) A peptide according to claim 43 wherein the histidine residue is phosphorylated.

48. (Amended) An antibody obtainable by the method of claim 46.

Pursuant to 37 CFR §1.121(c)(1)(iii), a marked up version of these claims accompanies this amendment.

51. (New) A method according to claim 4 wherein the epithelial cell sample from the patient is a lung cell sample or a nasal cell sample.

52. (New) A method according to claim 17 wherein the method is carried out *in vivo*.

53. (New) A method according to claim 19 wherein the method is carried out *in vivo*.

53. (New) A compound identified by the method of claim 17.

54. (New) A compound identified by the method of claim 19.

55. (New) A compound identified by the method of claim 21.

56. (New) A peptide according to claim 44 wherein the histidine residue is phosphorylated.

57. (New) An antibody obtainable by the method of claim 47.

**REMARKS**

In view of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

August 31, 2001  
Date

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APPENDIX

6. (Amended) A method according to [any one of Claims] claim 1 [to 5] wherein the epithelial cell sample from the patient is a lung cell sample or a nasal cell sample.

12. (Amended) A method according to [any one of Claims] claim 7 [to 11] wherein the epithelial cell sample from the patient is a lung cell sample or a nasal cell sample.

13. (Amended) A method according to [any one of Claims] claim 7 [to 11] wherein the effectiveness of a treatment for cystic fibrosis is being tested on the patient.

20. (Amended) A method according to [any one of Claims] claim 14 [to 19] wherein the method is carried out in vivo.

23. (Amended) A compound identified by the method of [any one of Claims] claim 14 [to 22].

32. (Amended) A peptide according to [any one of Claims 28 to] claim 31 which [has the sequence KENIIFGVSYDEYR] comprises SEQ. ID. NO. 1.

33. (Amended) A peptide according to [any one of Claims] claim 28 [to 32] further comprising a lipid-solubilising moiety.

36. (Amended) A peptide according to [Claims] claim 33 [or 34] wherein the lipid-solubilising moiety is a fatty acid.

39. (Amended) A pharmaceutical formulation

comprising a peptide according to [any one of Claims] claim 28 [to 37] and a pharmaceutically acceptable carrier.

40. (Amended) A method of treating cystic fibrosis or a chronic sputum producing disorder, the method comprising administering to a [the] patient an effective amount of a peptide according to [any one of Claims] claim 28 [to 37].

45. (Amended) A peptide according to claim 43 [or 44] wherein the [said] histidine residue is phosphorylated.

48. (Amended) An antibody obtainable by the method of claim 46 [or 47].

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